08/372,676

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	19 ~~20~~

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) Robert D. Budens (3) Demetra J. Mills

(2) Julie Reeves (4) Gladys Monroy

(5) J. Michael Schiff

Date of interview 6-11-96

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description: _____

Agreement ☐ was reached with respect to some or all of the claims in question. ☒ was not reached.

Claims discussed: All pending claims and proposed new claims 27-30 (see attachment)

Identification of prior art discussed: None

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

See Attached Description

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

Unless the paragraphs below have been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1–7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview.

☐ Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action.

Robert D. Budens
Examiner's Signature

PTOL-413 (REV. 1-84)

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ATTACHMENT TO EXAMINER INTERVIEW SUMMARY

June 11, 1996

The following is a summary of an interview between Examiners Robert Budens and Julie Reeves of the Patent And Trademark Office and Applicant's Attorneys, Demetra J. Mills, Gladys Monroy and J. Michael Schiff.

Applicant submitted proposed amendments to the pending claims and adding proposed new claims 27-30 (see attached proposed claims) in order to place the application in condition for allowance.

Examiner Budens indicated that claims 27 and 29 were considered allowable. However, the Examiner indicated that Applicant did not have sufficient written support for proposed claims 28 and 30. The Examiner indicated that the scope of claims 28 and 30 was broad and encompassed other species of antibodies including recombinant chimeric or humanized antibodies or antibodies with altered glycosylation and that there was no written description in the specification to establish that Applicant had contemplated antibody species other than the monoclonal antibody designated 1A7 obtained from hybridoma 1A7 (A.T.C.C Accession No. HB-11786).

Applicants did not point to support in the specification, but argued that the deposit of hybridoma 1A7 satisfied all the requirements of 35 U.S.C. § 112, first paragraph, by enabling those skilled in the art to practice the invention of claims 28 and 30.

Examiner Budens disagreed that the deposit would meet all the requirements of 35 U.S.C. § 112, first paragraph, for claims of broader scope than the deposit and that the specification must still provide sufficient written description to establish that Applicant had contemplated the claimed invention at the time of

filing. The Examiner suggested that Applicant submit a written response to enter the proposed amendments together with any relevant case law and arguments to support Applicant's position that the deposit would meet the requirements of 35 U.S.C. § 112, first paragraph, for claims 28 and 30.

Applicant further inquired with respect to claim 29, whether Applicant was required to claim the antibody as product by process or whether claims to "antibodies having all the characteristics of 1A7" would be acceptable.

Examiner Budens indicated that such language was usually used with respect to the hybridoma cell lines, not the antibodies, and that the Examiner would need to consider such language with respect to antibody claims.

The Examiner concluded the interview by informing Applicant that the **FINALITY** of the last Office Action would be removed in response to Applicant's persuasive petition, and that Applicant's arguments with respect to claims 28 and 30 should be submitted together with supporting case law for the Examiner's consideration.

ROBERT D. BUDENS
PRIMARY EXAMINER
GROUP 1800

To: Julie Reeves, Ph.D.
Biotechnology Patent Examiner, Group 1813
U.S. Patent & Trademark Office
FAX: (703) 305-7939

Re: US Patent Application 08/372,676

FOR DISCUSSION PURPOSES ONLY

Proposed claim revisions:

Cancel the following antibody and hybridoma claims without prejudice

1. (Previously amended) An antibody having the identifying characteristics of monoclonal antibody 1A7 produced by a cell deposited under ATCC Accession No. HB-11786.

10. An antibody producing cell deposited under ATCC Accession No. HB-11786 and the progeny thereof.

11. A purified antibody having identifying characteristics identical to an antibody produced by a cell according to claim 10.

12. Antibody purified from a cell according to claim 10.

Cancel the following pharmaceutical composition claims for prosecution in a continuation:

4. (Previously amended) A pharmaceutical composition comprising an antibody according to claim 1, and a pharmaceutically acceptable carrier.

13. The pharmaceutical composition of claim 4, wherein the antibody is capable of inducing an anti-GD2 antibody.

14. The pharmaceutical composition of claim 4, comprising an adjuvant.

15. The pharmaceutical composition of claim 14, wherein the adjuvant is selected from the group consisting of complete Freund's, incomplete Freund's adjuvant, and QS-21.

16. The pharmaceutical composition of claim 4, for treatment of a GD2 antigen associated cancer.

17. The pharmaceutical composition of claim 4, for treatment of melanoma, neuroblastoma, glioma, sarcoma, or small cell carcinoma.

18. (Previously amended) A pharmaceutical composition comprising an effective amount of an antibody according to claim 11.

19. The pharmaceutical composition of claim 18, comprising an adjuvant selected from the group consisting of complete Freund's adjuvant, incomplete Freund's adjuvant, and QS-21.

Maintain or amend the following claims:

7. (Three times amended) An antibody according to claim [1] 28 wherein said antibody further comprises a detectable label.

8. (Previously amended) An antibody according to claim 7, wherein said detectable label is selected from the group consisting of radiolabels, fluorescent labels and chemiluminescent labels.

9. (Previously amended) A diagnostic test kit for detecting an anti-GD2 antibody in a biological sample, comprising an antibody according to claim1 in a suitable container.

20. The diagnostic kit of claim 9, wherein the antibody is capable of binding anti-GD2.

21. The diagnostic kit of claim 9, wherein the antibody is labeled with a detectable label.

22. The diagnostic kit of claim 21, wherein the detectable labels selected from the group consisting of radiolabels, fluorescent labels, and chemiluminescent labels.

23. The diagnostic kit of claim 9, also comprising an anti-immunoglobulin reagent labeled with a detectable label.

24. The diagnostic kit of claim 9, wherein the biological sample is obtained from an individual suspected of having a GD2 antigen associated cancer.

25. The diagnostic kit of claim 9, wherein the sample is obtained from an individual suspected of having a cancer selected from the group consisting of melanona, neuroblastoma, glioma, sarcoma, and small cell carcinoma.

26. (Twice amended) The diagnostic kit of claim 9, wherein the biological sample is obtained from an individual [treated] administered with an antibody according to claim [1] 28.

Add the following claims:

27. (Added) Hybridoma designated 1A7 having ATCC Accession no. HB-11786.

28. (Added) An antibody with variable region amino acid sequences identical to those of monoclonal antibody produced by the hybridoma of claim 27.

29. (Added) Antibody purified from the hybridoma of claim 27.

30. (Added) Progeny of the hybridoma of claim 27 producing antibody according to claim 28.

May 24, 1996

FAX No 703-684-1124

Dear Demetra Mills:

1. Enclosed please find proposed claim language for application number 08/372,676 upon which the Office agrees.

2. The Applicant is correct in asserting that the finality of the previous Office Action was incorrectly imposed, accordingly, and with apologies, the finality of the previous Office Action has been withdrawn.

3. The following proposed claim language would be free from the prior art of record.

4. Claims 27-28 to be added. Claims 1, 4, 10-19 and 25-26 to be cancelled for the reasons discussed below. Claims 7, 8, 9 and 20-24 to be amended. Claims 7, 8, 9, 20-24 and 27-28 would be allowable upon amendment and completion of certain informalities, for example, clarifying/correcting the ATCC deposit number in the Chatterjee declaration.

5. Note: The term "progeny" encompasses the cultured cells, clones and subclones which have all the identifying characteristics of the deposited hybridoma 1A7.

Claim 27. Hybridoma designated 1A7 having ATCC Accession no. HB-11786 and progeny thereof having all the identifying characteristics of said hybridoma 1A7.

Claim 28. Monoclonal antibody produced by the hybridoma of claim 27.

Claims 7, 8, 9 and 20-24 to be amended to depend upon the antibody of claim 28.

Claims 1, 4, 10-19 and 25-26 to be cancelled for the following reasons:

Claims 1 and 10-12 are directed towards the hybridoma and antibody now claimed in proposed language that the PTO can accept in claims 27 and 28.

Claims 4 and 10-19 are directed towards the pharmaceutical composition. Prosecution will be reopened to address the issues of therapy if these claims are not cancelled.

Claim 25 recites neuroblastoma, glioma and sarcomas that the Examiner has not found in the specification. New Matter issue.

Claim 26 is directed towards the therapy issues that need to be addressed for Claims 4 and 10-19.

6. Please let me know if these claims are acceptable to the inventor so I process the application for allowance or, if the inventor wishes to maintain the pharmaceutical claims so that I can send out an Office Action to address the issue of therapy. I apologize for the delay.

Julie Reeeves
703-358-9070